

REMARKS

Withdrawn Claim 11

In view of the comments in section 1 of the Office Action on page 2, it appears that claim 12 was intended to be withdrawn and not claim 11. For now applicants identify claim 11 as withdrawn to not create any confusion, but clarification is requested.

Claim Amendments

From claim 11 a comma is removed.

In claim 7 in the last reply one of the formulae's location was replaced by an error message by a computer. The error message is deleted herein and the missing formula entered back into the claim. Support can be found, for example, in the original claims.

Entry of these amendments is respectfully and courteously requested as they attend merely to formality issues in the claims and their entry does not pose any search burden on the USPTO.

Priority and the Rejection Under 35 USC § 103

A certified translation of the priority application is attached. The rejection, which relies in part on Dougherty et al. (whose effective date is after the priority date of the present application) as allegedly providing the motivation for the modification of the compounds of Baumgarth et al., should be readily withdrawn.

The Rejections Under 35 USC § 112, first paragraph

Solvates/Hydrates

The terms solvates and hydrates have been deleted without prejudice or disclaimer. Applicants respectfully disagree with the allegations, but to advance prosecution to an expeditious allowance, cancelled these terms from the claims.

Mixture of Stereoisomers

The Office Action admits that "one can possess mixtures of isomers occur naturally during synthesis," nevertheless, rejects claim 22 directed to a mixture of stereoisomers of a compound of formula I according to claim 1. In view of the admission, it appears that the rejection of claim 22 is in error, and the withdrawal of said rejection is respectfully requested.

Isolated Stereoisomer

The Office Action rejects as allegedly not enabled the “isolated” stereoisomer of a compound of the claims. The Office Action alleges that the specification does not describe the isolation of stereoisomers and the Office Action cites Morrison, therein page 3, allegedly supporting the general allegation that stereoisomer separation can be extremely unpredictable due to its empirical nature.

Applicants respectfully disagree with both allegations.

The specification clearly teaches the compounds of formula I, which may have one or more centers of chirality, and therefore occur in various stereoisomeric forms. See, e.g., page 8. Furthermore, the specification on pages 21-22 clearly teaches that “the end product or even the intermediates can be separated into enantiomeric compounds by chemical or physical measures known to the person skilled in the art or even employed as such in the synthesis.” Techniques useful for separation taught in the specification include reaction with an optically active resolving agent (many examples of such agents are provided in the specification), and chromatographic enantiomer resolution with the aid of an optically active resolving agent (again for which many examples of such agents are provided in the specification). See pages 21-22 of the specification.

Even before discussing the allegations based on Morrison, applicants point out that Morrison was published in 1983, which does not reflect the state of the art of stereoisomer separation at the time of the filing of the present application which is about two decades later.

Moreover, Morrison does not support the allegation by the Office Action. Nothing in Morrison teaches that stereoisomer separation can be extremely unpredictable even generally, and especially not with regard to the compounds of the present claims. The copy of Morrison on page 3 provided by the USPTO has a section pen-marked, which is apparently the basis for the rejection, which reads “[r]esolution techniques, considered by some to be an art than science, have been the means of isolating many chiral compounds.” In context it is apparent that this sentence refers to early work done in the 1970s. See, e.g., the rest of the paragraph in Morrison. Moreover, even if considered an art rather than science, nothing in such a statement supports the allegations made by the Office Action, e.g., that separation is “extremely unpredictable.” Furthermore, Morrison clearly also teaches that by 1981 “the theory and practical aspects of resolution methods have been painstakingly organized, analyzed, expanded, and explained so that rational approaches likely to be successful can be identified and understood.” Additionally, Morrison describes various separation methods,

including achiral chromatographic methods, asymmetric transformations, etc. Nothing in the part of the reference provided by the Office Action teaches that these separation methods are “extremely unpredictable.”

As such, the USPTO has not carried its burden in establishing a lack of enablement. Therefore, the rejection should be withdrawn.

Rejoinder of Withdrawn Method/Process Claims

Applicants request the rejoinder of the withdrawn method and process claims in accord with the rejoinder provisions of the MPEP. See MPEP § 821.04, Rejoinder, which states that “if the elected invention is directed to the product and the claims directed to the product are subsequently found patentable, process claims [both process of making and using] which either depend from or include all the limitations of the allowable product will be rejoined.”

Examination of Withdrawn Product Claims

Applicants also request the examination of withdrawn product claim 17, and presumptively withdrawn product claim 12. These claims are directed to combinations of the allowed products of the elected claims and other components (further pharmaceutically active ingredient). As such, it is respectfully submitted that the pharmaceutical compounds/compositions of the elected claims and the combination thereof with other components are related as combination-subcombination. Since they are related as combination-subcombination, the standard for requiring restriction herein was not met, and therefore, the withdrawal thereof was improper.

In order to establish that combination and subcombination inventions are distinct, two-way distinctness must be demonstrated. To support a requirement for restriction, both two-way distinctness and reasons for insisting on restriction are necessary, i.e. separate classification, status, or field of search. See MPEP §808.02. If it can be shown that a combination, as claimed

- (1) does not require the particulars of the subcombination as claimed for patentability (to show novelty and unobviousness), and
- (2) the subcombination can be shown to have utility either by itself or in other and different relations, the inventions are distinct. When these factors cannot be shown, such

inventions are not distinct.
(Emphasis added.) (M.P.E.P. §806.05(c))

It is submitted that the first requirement for two-way distinctness is not established herein. The combination does require the particulars of the subcombination. The products of claims 17 and 12 all require the exact same compounds/compositions of the same scope as the subcombination claims of the elected group. To this end, the combination claims are even dependent upon the subcombination-product claims and the subcombination-products are an essential distinguishing feature of the combination-products.

It is respectfully submitted that when the relationship between the claimed subject matter and these withdrawn product claims is properly characterized, there is no basis for restriction herein. Thus, the restriction requirement should be withdrawn.

The Commissioner is hereby authorized to charge any fees associated with this response or credit any overpayment to Deposit Account No. 13-3402.

Respectfully submitted,

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